UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

R.S.B., a minor, by and through his Parent, and Next Friend, Stephanie Hammar, and STEPHANIE HAMMAR, Individually,

Plaintiffs,

v. Case No. 20-C-1402

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,

Defendants.

DECISION AND ORDER DENYING PLAINTIFFS' MOTION TO COMPEL

Plaintiffs R.S.B., a minor, and Stephanie Hammar, his parent, brought this action against Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp. (hereinafter "Merck"), alleging strict liability design defect, strict liability failure to warn, and negligence. Plaintiffs claim that, as a result of ingesting Merck's product, Singulair®, R.S.B. has suffered neuropsychiatric injuries. Before the Court is Plaintiffs' motion to compel Merck to respond to interrogatories and requests for production. Dkt. No. 51. For the following reasons, the motion will be denied.

BACKGROUND

Singulair, generically known as montelukast, is a prescription drug indicated for prophylactic and chronic treatment of asthma, acute prevention of exercise-induced bronchoconstriction, and for relief of symptoms of allergic rhinitis. 2d Am. Compl. ¶ 1, Dkt. No. 29. R.S.B. was prescribed Singulair, from approximately December 2010 to August 2012, when Merck's patent for the drug expired. Singulair was prescribed by R.S.B.'s doctor for the purpose

of treating R.S.B.'s asthma and hay fever symptoms. *Id.* at ¶ 7. After August 2012, R.S.B. began using generic montelukast. *Id.* at ¶ 11. In a separate decision, the Court has granted Merck's motion for summary judgment on Plaintiffs' claim against Merck for damages caused by R.S.B.'s ingestion of generic montelukast. The motion before the Court concerns what the parties have denominated "phase two" of the case which relates to Merck's defense of preemption as it applies to Merck's potential liability for injury caused by R.S.B.'s ingestion of Merck's Singulair. Plaintiffs contend that Merck has failed to fully respond to a number of their requests for production and interrogatories seeking information relevant to that defense.

As to Plaintiffs requests for production, Plaintiffs seek (1) "NDA #020829, #020830, and #021409;" (2) "[a]ll non-privileged communication to or from Merck regarding NDA #020829, #020830, and/or #021409;" (3) "[a]ll communications with the FDA regarding montelukast or Singulair;" (4) [a]ll clinical and preclinical trial data regarding montelukast, including INDs;" and (5) [a]ll neuropsychiatric adverse event reports regarding montelukast and Singulair." Dkt. No. 51 at 1. As for the interrogatories, Plaintiffs request that Merck (1) "identify all employees of its Regulatory Affairs department from 1996 to the present, including their job titles, and identify whether each person listed is currently employed with [Merck];" and (2) "[f]or every person listed in response to the question above who is not still employed with [Merck], please provide the last known address and telephone number." *Id.* Plaintiffs request this information in anticipation of Merck's motion for summary judgment on the ground that "federal law prohibited Merck from strengthening the label to add the warnings required by state law." *Id.* at 2.

On October 27, 2021, a week after Plaintiffs filed their motion to compel, the Court entered a protective order and an order regarding the production of documents and information. *See* Dkt. Nos. 54–55. That same day, Merck made its first production of documents, consisting of

approximately 455,000 pages. Dkt. No. 56 at 1 n.1, 2. This, according to Merck, has mooted Plaintiffs' motion. *Id.* at 2. After full briefing, the Court held a hearing and took the matter under advisement.

ANALYSIS

Rule 37 of the Federal Rules of Civil Procedure governs motions to compel. The Rule provides that, "[o]n notice to other parties and all affected persons, a party may move for an order compelling disclosure or discovery." Fed. R. Civ. P. 37(a)(1). Under Rule 26, parties may obtain discovery "regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). The information sought "need not be admissible in evidence to be discoverable." *Id.*

To understand the scope of discovery at issue in this motion, a brief recounting of the relevant federal framework is necessary. "[P]rospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1673 (2019) (citing 21 U.S.C. §§ 355(a), 355(b), 355(d)(7); 21 C.F.R. § 314.125(b)(6)). Because information about drug safety may change over time, drug manufacturers may "seek advance permission from the FDA to make substantive changes to their drug labels." *Id.* The "changes being effected" or "CBE" regulation, "permits drug manufacturers to change a label without prior FDA approval if the change is designed to 'add or strengthen a . . . warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm." *Id.* (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)). The term "newly acquired information" is defined as:

> data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses)

> if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3.

The CBE regulation is important here because "state laws requiring a label change are preempted unless the manufacturer could unilaterally add the new warning under the CBE regulation." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 814 (7th Cir. 2018) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011)). Plaintiffs contend the discovery they seek may contain "newly acquired information," relevant to the defense anticipated by Plaintiffs. The Court will address each request in turn.

A. Requests for Production #1 and #3

Plaintiffs' first and third requests for production "seek information that Merck provided to the FDA." Dkt. No. 51 at 7. In their first request for production, Plaintiffs seek New Drug Application (NDA) #020829, #020830, and #021409. But Plaintiffs acknowledge that they have received the NDAs as part of Merck's first round of production. Dkt. No. 59 at 1. Therefore, the Court finds this request moot.

Plaintiffs' third request for production seeks "[a]ll communications with the FDA regarding montelukast or Singulair." Dkt No. 51 at 1. Although relevant communications between Merck and the FDA are included in the NDAs, Plaintiffs assert that the request is not moot because the NDAs do not include communications prior to the approval of the first NDA in 1998. Merck acknowledges that this is true but contends that requiring production of communications prior to 1998 is "untethered to the preemption inquiry." Dkt. No. 56 at 18. This is so, Merck claims, because the relevant time period for a CBE inquiry is the time between FDA approval of the relevant label and R.S.B.'s last use of the product. In this case, the alleged relevant time period

would be from May of 2010, the month in which the FDA approved the relevant label, to August of 2012, the month R.S.B. last used Singulair.

The Court agrees with Merck that the relevant period is the time between when Singulair's label was last approved by the FDA and the date R.S.B. last used Singulair. This approach finds support from courts across the country. *See, e.g.*, *Silver v. Bayer Healthcare Pharm., Inc.*, No. 2:19-cv-3495-DCN-MHC, 2021 WL 4472857, *9 (D.S.C. Sept. 30, 2021) ("Silver must allege that new information arose sometime after March 2015—when the FDA last approved Eovist's label—and December 2016—when Silver was injected with Eovist."); *Goodell v. Bayer Healthcare Pharm., Inc.*, No. 18-cv-10694-IT, 2019 WL 4771136 (D. Mass. Sept. 30, 2019) ("*Celexa* thus requires Plaintiff to provide plausible allegations of 'newly acquired information' that manifested after the FDA's approval of the Magnevist label but before Plaintiff's injury."). Plaintiffs fail to demonstrate how communications between Merck and the FDA prior to 1998 could impact Merck's ability to unilaterally change their label for Singulair through the CBE regulation. Because these communications were in existence prior to the relevant label and because the FDA necessarily would have had knowledge of the information contained in the communications, Plaintiffs are not entitled to the pre-1998 information sought in their third request for production.

B. Requests for Production #2, #4, and #5

Plaintiffs contend that the remainder of their requests for production are either designed to "directly seek newly acquired information" or to "lead to the discovery of newly acquired information." Dkt. No. 51 at 8–9. Plaintiffs' second request for production seeks "[a]ll non-privileged communication to or from Merck regarding NDA #020829, #020830, and/or #021409." Dkt. No. 51 at 1. The fourth request for production seeks "all clinical and preclinical trial data

regarding montelukast, including INDs." *Id.* And the fifth request for production seeks "[a]ll neuropsychiatric adverse event reports regarding montelukast or Singulair." *Id.* All of these requests suffer from the same defect: Merck has already provided the relevant information in its production of its regulatory file. Plaintiffs' proffered reasons for seeking additional information are based on a misunderstanding of what can constitute "new analyses of previously submitted data." 21 C.F.R. § 314.3.

At the outset, Merck has provided sufficient responses to these requests. As to the second request for production, the request is moot to the extent it seeks communications between Merck and the FDA because the NDAs necessarily encompass any pertinent FDA-related communications. The remainder of the request, that Merck produce any communication with any third party regarding the NDAs, is overbroad and unnecessarily disproportionate to the needs of the case. Plaintiffs seek these communications on the ground that may lead to the discovery of evidence that shows "Merck ignored red flags and/or willfully chose not to follow up on study data showing the effect of montelukast on the brain." Dkt. No. 51 at 10. Any of these previously ignored red flags, Plaintiffs claim, may serve as a "basis for new analysis of previously acquired data." *Id.* But requiring Merck to examine two decades of communications on the speculative basis that the communications *may* contain unfavorable study data is not a sufficient reason to require Merck to undertake the production of what is likely to be tens, if not hundreds, of thousands of pages. Because Plaintiffs have the NDAs, they necessarily have "a description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant *from any source*, foreign or domestic." 21 C.F.R. § 314.50(d)(5)(iv) (emphasis added). Therefore, it appears that Plaintiffs have access to exactly what they seek.

Merck has also provided sufficient responses to the fourth and fifth requests for production. Merck asserts that it is producing all neuropsychiatric adverse event reports. Dkt. No. 56 at 19. This moots Plaintiffs' fifth request for production. As a result of producing the NDAs, Merck claims that it has provided Plaintiffs with "all clinical and preclinical trial data" because the NDAs include all pertinent safety information regarding the product, including the data and analyses of 46 clinical studies and 80 preclinical studies. *Id.* Because NDAs are required to include "a description and analysis of each controlled clinical study pertinent to a proposed use of the drug, including the protocol and a description of the statistical analyses used to evaluate the study," 21 C.F.R. § 312.50(d)(5)(ii), as well as a "description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic," 21 C.F.R. § 314.50(d)(5)(iv), the Court concludes that Plaintiffs' fourth request for production is moot as well.

Both in their brief and at the motion hearing, Plaintiffs requested that the Court require Merck to "certify" that they produced all of their documents related to the fourth and fifth requests for production. At the motion hearing, Plaintiffs' counsel asked the Court if it would be willing to ask Merck if it produced all clinical and preclinical trial data, even if that question was limited to data after 1998. Tape No. 111621 at 20:46. Merck's counsel responded, "I can absolutely say that." *Id.* at 20:58. Even had that exchange not occurred, Federal Rule of Civil Procedure 26(g)(1)(A) notes that, by signing a discovery response, an attorney certifies "with respect to the disclosure, it is complete and correct as of the time it is made." By signing the response, Merck's attorneys were certifying that his response to the request was complete and correct. Additional certification by Merck is not required.

But even had Merck failed to provide sufficient responses to Plaintiffs' requests, the result would be the same. For each of the requests, Plaintiffs' proposed justification for seeking the information is that it "could be a basis for new analysis of previously submitted data." Dkt. No. 51 at 9. At the motion hearing, Plaintiffs' counsel explained that she had experts who wished to see raw testing data so that Plaintiffs could see "how the information should be summarized differently" or "could be summarized differently." Tape No. 111621 at 11:25. But "new analyses of previously submitted data" does not mean an analysis conducted by an expert in preparation for litigation with the benefit of hindsight. Instead, it refers to the scenario in which "the sponsor [of a drug] submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to the FDA." *Wyeth*, 555 U.S. at 569 (quoting 73 Fed. Reg. 49607).

In other words, Plaintiffs are not entitled to create their own "newly acquired information" through the use of experts; rather, they must point to the *existence* of newly acquired information that Merck possessed during the relevant time period. *See, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) ("CBE changes rest on the *existence* of 'newly acquired information.'" (quoting 21 C.F.R. § 314.70(c)(6)(iii))) (emphasis added); *Goodell*, 2019 WL 4771136, at *4 ("Without factual allegations that Bayer *had* new information in this time period such that it could have or should have amended the label pursuant to the CBE regulation, the complaint is barred as preempted.") (emphasis added). Plaintiffs have not pointed to any specific study, data, or any other evidence that Merck allegedly had, or should have had, in the course of making their discovery requests. Absent evidence suggesting that Merck withheld specific data or studies, the Court will not require them to comb through every conceivable document in their possession to satisfy Plaintiffs' expansive discovery requests. The Court

concludes that Merck's response to Plaintiffs' second, fourth, and fifth requests for production is sufficient.

C. Interrogatories #2 and #3

Finally, Plaintiffs seek responses to two interrogatories which ask Merck to "identify all employees of its Regulatory Affairs department from 1996 to the present, including their job titles, and identify whether each person is currently employed with [Merck]." Dkt. No. 51 at 1. They further request that, "[f]or every person listed in response to the question above who is not still employed with [Merck], please provide the last known address and telephone number." *Id.* Plaintiffs note that this request is now limited only to those employees who had responsibility for Singulair. Dkt. No. 59 at 1. Through this request, Plaintiffs seek evidence that Merck "submitted unfavorable data to FDA buried under a mountain of favorable data or at least downplayed the significance of the unfavorable data. New analysis of previously submitted information would be 'newly acquired information.'" Dkt. No. 51 at 10.

If in fact Merck submitted unfavorable data to the FDA or if it downplayed the significance of that data, Plaintiffs would have access to that information by virtue of being provided the NDAs. Notably, Plaintiffs do not argue that they seek this information because they believe Merck *withheld* unfavorable data from the FDA, but rather because they believe that Merck may have "buried" the unfavorable data by submitting a voluminous amount of favorable data. Because the NDAs contain the data and analyses submitted to the FDA as part of preclinical and clinical testing, Plaintiffs have access to the supposedly unfavorable information they seek. More importantly, however, is the fact that Merck has already provided Plaintiffs with the names and employment dates of each regulatory liaison who had responsibility for Singulair over its entire lifecycle. *See* Dkt. No. 56-5 at 2. It appears Merck has already given Plaintiffs access to the individuals who

would have knowledge of any unfavorable data that may have been buried by Merck. Plaintiffs do not explain how access to every possible regulatory affairs employee who worked on Singulair would provide them with the specific piece of "newly acquired evidence" sought. Absent something more than a mere hunch that Merck had some form of "newly acquired evidence" in their possession, the Court will not require Merck to provide more information than they already have.

CONCLUSION

In sum, the Court concludes that Merck has conducted a reasonable and diligent search in response to Plaintiffs' discovery requests. Merck has provided sufficient responses to each request and Plaintiffs have failed to demonstrate that they are entitled to the information they seek. Therefore, Plaintiffs' motion to compel discovery requests (Dkt. No. 51) is **DENIED**. Plaintiffs' Rule 7(h) expedited non-dispositive motion to reset the phase two discovery and briefing deadlines (Dkt. No. 60) is **GRANTED-IN-PART** and **DENIED-IN-PART**. Plaintiffs will have ninety (90) days after Merck has provided all phase two written discovery to review the responses and to complete whatever depositions are appropriate. Merck's motion for summary judgment on grounds of preemption is due thirty (30) days thereafter.

SO ORDERED at Green Bay, Wisconsin this 27th day of December, 2021.

s/ William C. Griesbach
William C. Griesbach
United States District Judge